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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,682	08/27/2001	David E. Townsend	150026.464	4343

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EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,682

Applicant(s)

TOWNSEND, DAVID E.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-16 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-7, 10-16 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's Request for Continued Examination and amendment filed on July 7, 2004 has been received and entered into the case. Claim is canceled; claims 1 – 7 and 10 – 16 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Objections

Claim objections have been withdrawn due to amendment.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 – 7 and 10 – 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townsend.

Applicant claims a composition for detecting a target microorganism, the composition comprising a conditionally detectable marker that is a redox dye, and a substrate for an aminopeptidase that is substantially absent from a target microorganism; wherein the substrate comprises a signal moiety linked to the substrate that provides a detectable signal when cleaved by substantially all non target microorganisms. The target microorganism is a bacteria, yeast,

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mold, fungi, protozoa or virus, specifically bacteria selected from Salmonella, Listeria, E. coli OH157, Campylobacter, Staphylococcus aureus, Cryptosporidium or Giardia. The preferred bacteria are Campylobacter. The conditionally detectable marker is detectable by a color change, wherein the change in color is produced by a biochemical reduction of tetrazolium red. The enzyme is specifically L-alanine aminopeptidase; and the substrate is selected from a disclosed group, specifically L-alanine-7-amido-4-methylcoumarin. The non-target microorganisms are substantially all non-Campylobacter species. The composition further comprises a growth supporting medium for target microorganisms, which contains all necessary nutrients and growth conditions to support target organism.

Townsend teaches a composition for detecting viable bacteria, yeasts or fungi (p.11) in a test sample, the composition comprising substrates and detectable markers (abstract). Townsend teaches examples of detectable markers (p.7, claims) such as tetrazolium, phenol red and neutral red (redox dye), which are chemically reduced to produce a color change (p.2, 7, claims) and bacterial substrates that change color or fluoresce upon bacterial hydrolysis (p.6, 9), or are conditionally detectable markers. Bacteria are selected from Staphylococcus aureus, E. coli, and gram negative bacteria of Bergey's Manual of Systematic Bacteriology, 1989 (p.8-9) (includes Salmonella, Listeria, Campylobacter, Cryptosporidium, S. aureus). Townsend teaches the claimed substrates (p.19), preferring L-alanine-7-amido-4-methylcoumarin, and L-alanine-aminopeptidase as the enzyme (p.9). The composition further comprises the nutrients necessary to support growth of the microorganisms (p.3).

Although Townsend does not specifically teach the compositions comprising the claimed dyes, Townsend does teach the compositions to include color markers and that effective markers

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include tetrazolium, phenol red and neutral red. Therefore at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to use tetrazolium red or the redox dyes in the composition of Townsend with a reasonable expectation for successfully detecting microorganisms.

3. Claims 1 – 7 and 10 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townsend in view of Stern.

Applicant claims a composition for detecting a target microorganism, the composition comprising a conditionally detectable marker that is a redox dye, and a substrate for an aminopeptidase that is substantially absent from a target microorganism; wherein the substrate comprises a signal moiety linked to the substrate that provides a detectable signal when cleaved by substantially all non target microorganisms. The target microorganism is a bacteria, yeast, mold, fungi, protozoa or virus, specifically bacteria selected from Salmonella, Listeria, E. coli OH157, Campylobacter, Staphylococcus aureus, Cryptosporidium or Giardia. The preferred bacteria are Campylobacter. The conditionally detectable marker is detectable by a color change, wherein the change in color is produced by a biochemical reduction of tetrazolium red. The enzyme is specifically L-alanine aminopeptidase; and the substrate is selected from a disclosed group, specifically l-alanine-7-amido-4-methylcoumarin. The non-target microorganisms are substantially all non-Campylobacter species. The composition further comprises a growth supporting medium for target microorganisms, which contains all necessary nutrients and growth conditions to support target organism and antibiotics to suppress growth of non target microorganisms.

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Townsend teaches a composition for detecting viable bacteria, yeasts or fungi (p.11) in a test sample, the composition comprising substrates and detectable markers (abstract). Townsend teaches examples of detectable markers (p.7, claims) such as tetrazolium, phenol red and neutral red (redox dye), which are chemically reduced to produce a color change (p.2, 7, claims) and bacterial substrates that change color or fluoresce upon bacterial hydrolysis (p.6, 9), or are conditionally detectable markers. Bacteria are selected from *Staphylococcus aureus*, *E. coli*, and gram negative bacteria of Bergey's Manual of Systematic Bacteriology, 1989 (p.8-9) (includes *Salmonella*, *Listeria*, *Campylobacter*, *Cryptosporidium*, *S. aureus*). Townsend teaches the claimed substrates (p.19), preferring L-alanine-7-amido-4-methylcoumarin, and L-alanine-aminopeptidase as the enzyme (p.9). The composition further comprises the nutrients necessary to support growth of the microorganisms (p.3).

Although Townsend does not specifically teach the compositions comprising the claimed dyes, Townsend does teach the compositions to include color markers and that effective markers include tetrazolium, phenol red and neutral red. Therefore at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to use tetrazolium red or the redox dyes in the composition of Townsend with a reasonable expectation for successfully detecting microorganisms.

Townsend does not teach the composition further comprising antibiotics. However, Stern teaches compositions for detecting viable gram negative bacteria comprising antibiotics for suppressing other, non target microorganisms (abstract). Stern teaches the inclusion of antibiotics allows the characterization of the target microorganism (col.1 line 25-36). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Stern to

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include antibiotics in the composition of Townsend with a reasonable expectation for successfully detecting viable target bacteria.

Response to Arguments

Applicant argues that Townsend does not teach all of the elements of the claims, specifically that the substrate is not absent from the target organism, that redox dyes are not taught in combination with substrates, and that the dyes are not taught as indicators. Applicant additionally argues that Stern does not remedy the deficiencies.

However, these arguments fail to persuade because Townsend specifically teaches the composition to include color or fluorescent markers (p.2, 7, claims) and provides the claimed dyes as examples of such color indicators. Regarding applicant's argument that the substrate is not absent a target microorganism, the compositions are structurally the same. Townsend specifically teaches the claimed substrates in combination with color indicators as claimed. It is noted that intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112). Therefore, the claims are rejected over the cited references.

Conclusion

4. This is an RCE of applicant's earlier Application No. 09/940,682. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

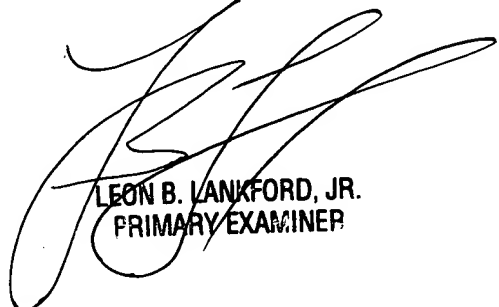
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); alt. F (7:00-3:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis; rad
July 22, 2004.



LEON B. LANKFORD, JR.
PRIMARY EXAMINER